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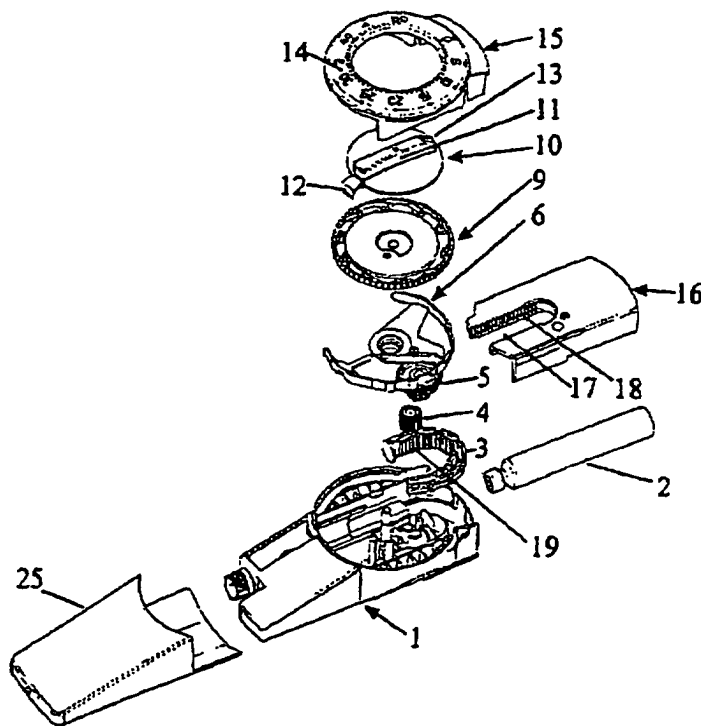
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(54) Title: DOSE SETTING LIMITER



(57) Abstract: A limiting mechanism which prevents the setting of a dose, which exceeds the amount of liquid left in a cartridge of an injection device is disclosed. The injection device is the type where a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device. The dose setting member interfaces the driver such that the dose setting member can be rotated in one direction without rotating the driver. The dose is injected by rotating back the dose setting member which during the backward rotation carries the driver with it. Rotating the driver causes the piston rod to move forward inside the cartridge and expel some of the liquid contained in the cartridge. The driver is provided with a track having a length which is related to the total amount of liquid in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member. Each time a dose is set and injected, the track follower moves further into the track. When the track follower reaches the end of the track the dose setting member cannot be rotated

further, and a dose larger than the remaining liquid in the cartridge cannot be set.

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— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

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DOSE SETTING LIMITER

The invention relates to injection devices wherein the content of a cartridge injected as a number of individually set doses.

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Such devices has a dose setting mechanism by which the doses are set for subsequent injecting when an injection button is operated. This can be obtained by moving a carrier along a piston rod a distance proportional to the wanted dose and subsequently move the carrier back to its original position so that the carrier carries the piston rod with it instead of being
10 moved along said piston rod.

From EP 327 910 is known a syringe by which a dose is set by screwing a nut member up along a threaded piston rod away from a stop in a housing. The set dose is injected by pressing the end of the nut member which forms an injection button whereby the nut mem-
15 ber is moved back to abutment with the stop again. During the latter movement of the nut member the piston rod is carried along by the nut which do no move relative to this piston rod during the injection.

When a dose is set it is convenient if a limiting device is provided which makes it impossible
20 to set a dose which exceeds the amount of medicament which is left in the cartridge. In EP 327 910 this is obtained by the fact that the thread of the piston rod has such a length that the cartridge is just emptied when the nut is screwed to the end of the thread and the then pressed home to its abutment with the stop. By setting a dose the nut can only be screwed to the end of the thread and thereby the size of the last dose is limited to comprise the re-
25 maining amount in the cartridge.

The distance the injection button has to be moved corresponds to the distance the piston in the cartridge has to be moved to inject the set dose. Especially by larger cartridges with a large cross section diameter this distance can be very short. To obtain a larger movement of
30 the injection button a sort of gearing may be used so that the distance the injection button have to be moved is proportional with the injected dose but is a number of times the movement of the piston in the cartridge.

EP 608 343 describes an example of such a geared dose setting and injection mechanism.

In this device the carrier do not co-operate directly with the threaded piston rod but with a driver element which can move the piston rod when a set dose is injected. In this device the driver element comprises a nut member which is fixed against axial displacement in the injection device. The thread of the nut member engage an outer thread of the piston rod which is secured against rotation in the injection device . By the setting of a dose the carrier is rotated away from a stop to which it is returned when the injection button is operated. During its return the carrier rotates the driver element which moves the piston rod further into the cartridge to press the piston of this cartridge so that a set amount of the medicament in the cartridge is pressed out through an injection needle at the distal end of said cartridge. As the nut member is not moved relative to the piston rod during the setting of a dose a limiting construction as described above cannot be provided limiting the dose so it does not exceed the amount of liquid left in the injection device.

An object of the invention is to provide a limiting mechanism which prevents setting of a dose which exceed the amount of liquid left in a cartridge of an injection device of the geared type wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver element with it to rotate this driver element which moves the piston rod forward.

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Such a mechanism is according to the invention characterised in that the driver element is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of said dose setting member. During the setting of a dose the track follower will be advanced in the track of the driver to a position depending on the set dose as during dose setting the dose setting member and the driver are rotated relative to each other. As during the injection the driver follows the rotation of the dose setting member, the pin of the dose setting member will keep its position in the track of the driver when the set dose is injected. The length of the track is so adapted that the pin reaches the end of the track and makes an increase of the set dose impossible when a dose is set which corresponds to the amount of liquid remaining in the cartridge.

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According to the invention the driver may be disk shaped and have a spiral shaped track which is engaged by a cam on a member which is flexibly coupled to the dose setting member so that the pin can be moved radially when it follows the track of the driver.

- 5 In another embodiment of the invention the driver may be cylindrical and have a helical track which is engaged by a cam on the dose setting member which is a cylinder concentric with the driver.

The track may be provided as a thread in the driver and the track follower may be a nut
10 shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver. When a dose is set the dose setting member is screwed with its thread along the thread of the driver. The limitation of the set dose is obtained by giving the threads an appropriate length.

- 15 In the following the invention will be explained in further details with references to the drawing, wherein

Figure 1 shows an exploded view of a syringe with a dose limiter according to the invention,

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Figure 2 an enlarged view of the dose setting element and the driver element of the syringe in figure 1.

Figure 3 shows the dose setting member, the driver, and the track follower of another embodiment of an injection syringe.
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The syringe in figure 1 comprises a housing 1 accommodating a cartridge 2 from which the content can be pressed out by a piston rod 3 which is by injection via gear wheels 4 and 5 advanced a distance corresponding to a dose set by dose setting. A dose setting member 6
30 is provided with a toothed wheel 7 surrounding a central bore through which a pinion 8 on a driver 9 projects as it is shown in figure 2. The dose setting element 6 is operated through an operation element 10 which has a finger grip 11, a carrier 12 which engages the dose setting member 6, and a arrow 13 pointing on a scale 14 provided on a Lid 15 which forms a part of

the housing 1. Figure 1 further shows a cap 25 which can be put on to protect a not shown needle which may be mounted on the syringe, and an injection button 16 which is sliding mounted in the housing 1 and which has a recess 17 which is on one of its side surfaces provided with a cogging 18.

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In the assembled syringe the toothed wheel 7 on the dose setting member 6 engages the cogging 18 of the button element 16 whereas the pinion 8 on the driver 9 engaged the part with the large diameter of the gear wheel 5 the part of which with the small diameter engages the other gear wheel 4 which further engages a cogging 19 on the piston rod 3.

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The driver member 9 is provided with pawl 26 which with not shown teeth in the housing forms an unidirectional coupling allowing the driver 9 to rotate only in the direction by which the piston rod 3 is advanced into the cartridge 2. A ratchet is provided by saw tooth shaped protrusions on the dose setting element 6 engaging a saw tooth cogging 27 at the perimeter of the driver 9, this ratchet being so oriented that only rotation of the dose setting member 6 in the direction in which the driver 9 can move is transmitted from the dose setting member 6 to the driver 9. By rotation of the dose setting member 6 in the opposite direction the teeth of the ratchet parts will ride over each other.

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20 To set a dose the finger grip 11 of the operation element 10 is gripped and the element 10 is rotated clockwise until the arrow point at the wanted dose on the scale 14. As mentioned this rotation will make the ratchet parts of the dose setting element and the driver ride over each other. If the dose setting member 6 is rotated in the clockwise direction to reduce the set dose, the ratchet will cause transmission of the rotation from the dose setting member 6 to the driver 9 but the when a torque in this direction is transmitted from the operating element through the carrier 12 to the dose setting member 6, this dose setting member is deformed so that the protrusion on the dose setting member 6 is drawn out of its engagement with the toothing 27 of the driver 9 and an anticlockwise rotation of the dose setting member 6 is allowed without the rotation being transmitted to the driver 9.

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Due to the engagement between the toothed wheel 7 on the dose setting member 6 and the cogging 18 of the injection button 16 this button will be lifted from the end of the housing 1 when a dose is set and will be lowered when a dose is reduced.

When the injection button 16 is pressed to inject a set dose the engagement between the toothed wheel 7 on the dose setting member 6 and the cogging 18 of the injection button 16 will cause the dose setting member 6 to rotate in an anticlockwise direction. As the torque is not transmitted to the dose setting member 6 by the operating element 10, the ratchet coupling between the dose setting member 6 and the driver 9 will be active and the driver 9 will be rotated with the dose setting member 6 in the anticlockwise direction and will drive the piston rod 3 into the cartridge.

As it is seen in figure 2 the disk shaped driver 9 has in its side facing the dose setting member 6 a spiral shaped track 20 which is engaged by a cam 21 provided at the end of an arm 22 which is by a flexible beam 23 fastened to the dose setting member 6 so that the arm 22 can swing to let the cam 21 move in the radial direction of the driver 9. When the dose setting member 6 during the setting of a dose is rotated relative to the driver 9 the cam is moved along the track 20 whereas the cam during the injection due to the concomitant rotation of the dose setting member 6 and the driver 9 remains in its position in the track 20 obtained during the dose setting. This way the position of the cam in the track reflects the total amount of medicine administered. When the cam 21 abuts the end wall 24 of the track 20 the set dose cannot be increased and by adapting the length of the track to the total amount of medicine in the cartridge it is ensured that a dose larger than the amount of medicine remaining in the cartridge cannot be set.

Figure 3 shows a dose setting member 30 surrounding a driver 31 of another embodiment of a dose setting limiter. The dose setting member 30 is cylindrical and is on its outer wall provided with a helical track 29 which is designed to co-operate with a helical inner ridge in a not shown housing so that the dose setting member 30 is screwed outward in said housing when rotated to set a dose and inward in said housing when rotated to reduce a too large set dose. During the dose setting rotation the dose setting member 30 is rotated freely relative to the driver 31 which it surrounds. Between the dose setting member 30 and the driver 31 a nut member 32 is coupled which can when it is rotated relative to the driver 31 be screwed up along this driver which is at its outer surface provided with a helical track 33. At its outer wall the nut member 32 is in the axial direction provided with a recess 34 which is engaged by an ridge 35 in the axial direction on the inner side of the dose setting element 30.

During the setting of a dose the nut member 32 is due to the engagement between the ridge 35 and the recess 34 rotated with the dose setting member 30 relative to the driver 31 so that the position of the nut member 32 on this driver is dependent on the dose set. When the dose is injected by pressing a not shown injection button which is placed in an end part 36 of the dose setting member 30 this button presses a flange 37 at an end of the driver 31 into engagement with coupling teeth 38 at the bottom of said end part 36 of the dose setting member 30. On its lower not visible side the flange 37 is provided with coupling teeth corresponding to the coupling teeth 38 of the dose setting member 30 and when the dose setting member 30 is due to the engagement between the track 29 in the dose setting member 30 and the ridge in the housing forced to rotate relative to the housing when it is pressed into said housing the rotation will be transmitted to the driver 31 which due to the engaging coupling teeth is forced to rotate with the dose setting member and during this rotation the nut member 32 will maintain its position on the driver 31. This way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses. When the length of the helical track 33 in the driver 31 is adapted to the amount of medicine in a cartridge the nut member 32 will reach the end of the track 33 and stop for setting a dose larger than the amount remaining in the cartridge.

Claims

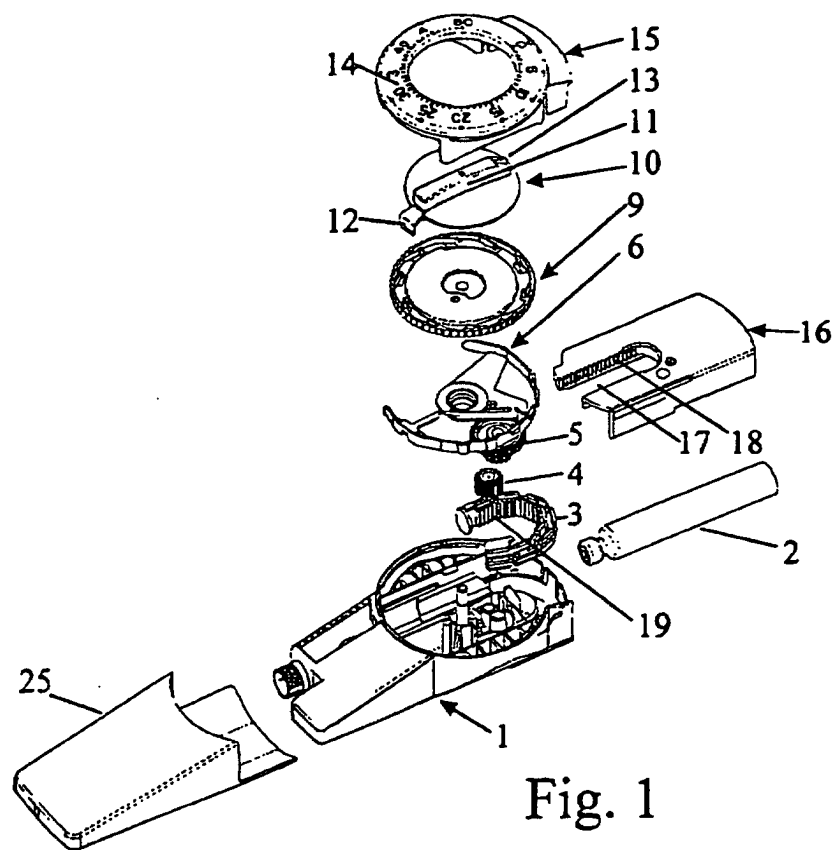
- 5 1. A limiting mechanism which prevents setting of a dose which exceeds the amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, characterised in that
- 10 the driver is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member.
2. According to claim 1, characterised in that the driver is disk shaped and has a spiral
- 15 shaped track which is engaged by a cam flexibly coupled to the dose setting element so that said cam can be moved radially when it follows the track of the driver element.
3. A limiting mechanism according to claim 1, characterised in that the driver is cylindrical and has a helical track which is engaged by a cam coupled to the dose setting member
- 20 which is a cylinder concentric with the driver.
4. A limiting mechanism according to claim 3, characterised in that the track is provided as a thread in the driver and that the track follower is a nut shaped member coupled to the dose setting member and provided with a thread engaging the thread of the driver.

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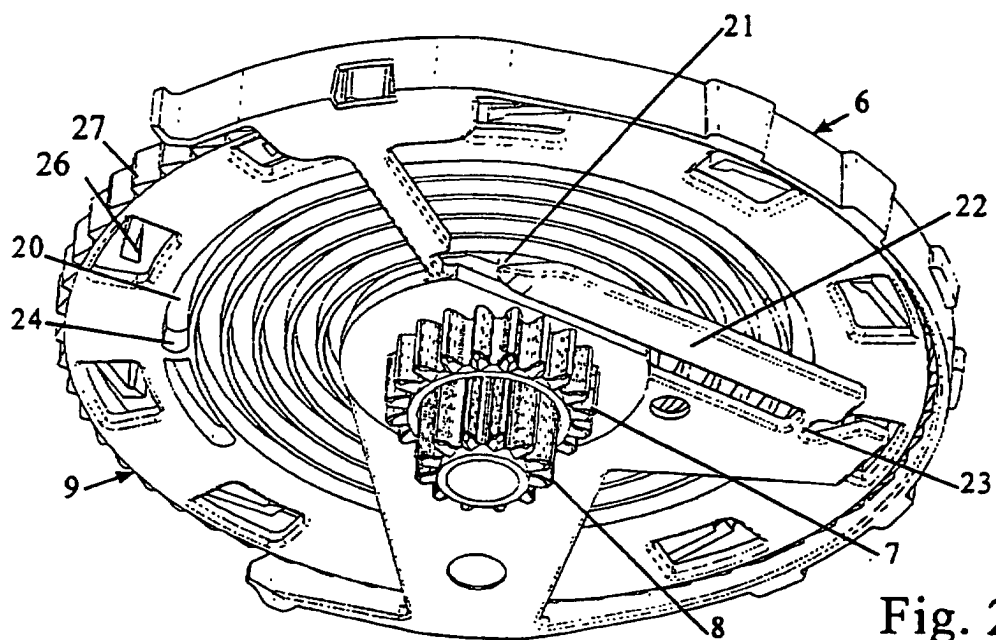


Fig. 2

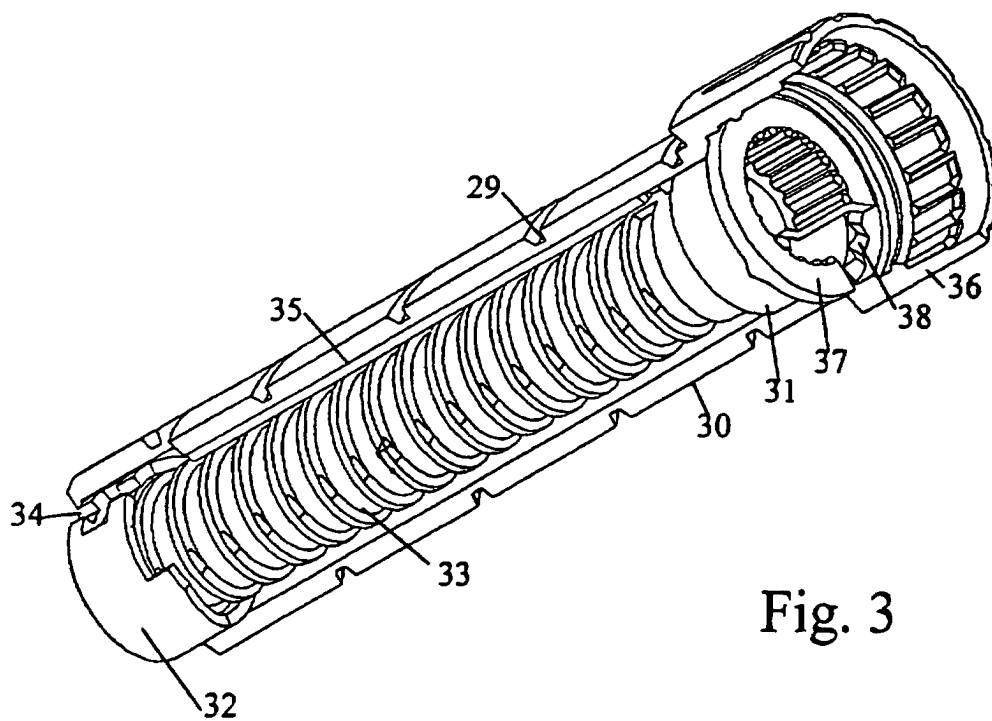


Fig. 3

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 5/315, A61M 5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8907463 A1 (D.C.P. AF 1988 A/S), 24 August 1989 (24.08.89) --	1-4
A	WO 9307922 A1 (NOVO NORDISK A/S), 29 April 1993 (29.04.93) --	1-4
A	WO 9810813 A1 (NOVO NORDISK A/S), 19 March 1998 (19.03.98) -----	1-4

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8907463 A1	24/08/89	AT 74777 T	15/05/92
		AU 618581 B	02/01/92
		AU 3066689 A	06/09/89
		BR 8907240 A	05/03/91
		CA 1305003 A	14/07/92
		CN 1025719 B	24/08/94
		CN 1035055 A	30/08/89
		CS 8900905 A	16/12/92
		CZ 278561 B	16/03/94
		DD 283332 A	10/10/90
		DE 68901190 D	00/00/00
		DK 69288 A	11/08/89
		DK 166948 B	09/08/93
		EP 0327910 A,B	16/08/89
		SE 0327910 T3	
		ES 2030541 T	01/11/92
		FI 94930 B,C	15/08/95
		FI 903893 D	00/00/00
		GR 3004398 T	31/03/93
		HR 930507 A,B	30/04/95
		HU 54064 A	28/01/91
		HU 206272 B	28/10/92
		HU 891454 D	00/00/00
		IE 61515 B	16/11/94
		IL 89189 A	27/02/94
		JP 2726536 B	11/03/98
		JP 3503129 T	18/07/91
		KR 9615612 B	18/11/96
		MX 170604 B	01/09/93
		NO 166519 B,C	29/04/91
		NO 903508 A	09/10/90
		NZ 227895 A	26/03/91
		PT 89669 A,B	04/10/89
		RU 2053798 C	10/02/96
		SI 8910315 A	30/04/97
		SK 278253 B	05/06/96
		US 4973318 A	27/11/90
		YU 31589 A	30/06/91
		ZA 8900902 A	25/10/89

INTERNATIONAL SEARCH REPORT

Information on patent family members

27/12/00

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Patent document cited in search report			Publication date	Patent family member(s)		Publication date
WO	9307922	A1	29/04/93	AT	160946 T	15/12/97
				AU	662021 B	17/08/95
				AU	2795192 A	21/05/93
				CA	2119913 A	29/04/93
				DE	69223521 D,T	18/06/98
				DK	175491 D	00/00/00
				DK	608343 T	24/08/98
				EP	0608343 A,B	03/08/94
				SE	0608343 T3	
				ES	2112915 T	16/04/98
				GR	3026174 T	29/05/98
				JP	7500039 T	05/01/95
				RU	2091087 C	27/09/97
				US	5626566 A	06/05/97
WO	9810813	A1	19/03/98	AU	726722 B	16/11/00
				AU	4199897 A	02/04/98
				BR	9711784 A	24/08/99
				CN	1230125 A	29/09/99
				CZ	9900877 A	16/06/99
				EP	0927057 A	07/07/99
				HU	0000091 A	28/05/00
				NO	991167 A	10/03/99
				PL	332042 A	16/08/99
				US	5947934 A	07/09/99